EFS-Web Receipt date: 12/14/2006

10634408 - GAU: 1633

PATENT

I hereby certify that on December 14, 2006, Applicant: Jong-Gu Park et al. which is the date I am signing this certificate, I Serial No.: 10/634,408 am transmitting this correspondence and all Filed: August 5, 2003 attachments electronically identified Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

/Andrew Lee/

Andrew Lee

Title: NEPHRITIS TREATMENT BY

**GENE THERAPY** 

Examiner: Kelly, Robert M.

Art Unit: 1633

Attorney Docket No.: 57354-08USA

## IN THE UNITED STATES OF AMERICA PATENT OFFICE

Mail Stop Patent Application Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed below and on the attached form PTO/SB/08B (substitute for form 1449/PTO) are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. The filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), as an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists. The filing of this Information Disclosure Statement shall not be construed as an admission against interest in any manner. Copies of the cited documents were submitted together with an Information Disclosure Statement on August 5, 2003. This Information Disclosure Statement is submitted to correct the previously filed Information Disclosure Statement filed on August 5, 2003. This Information Disclosure Statement includes titles of the references which were missing in the original submission.

PATENT 57354-08USA

## **English Language Documents:**

Kamanna et al., "Hyperlipidemia and kidney disease: Concepts derived from histopathology and cell biology of the glomerulus," *Histol Histopathol*, 13:169-179 (1998).

Del Prete et al., "Molecular Biology of Diabetic Glomerulosclerosis," Nephrol Dial Transplant, 13(8):20-25 (1998).

Wehrmann et al., "Long-term prognosis of focal sclero-Sing glomerulonephritis. An analysis of 250 cases with particular regard to tubulointerstitial changes," *Clinical Nephrology*, 33(3):115-122 (1990).

Mackensen-Haen et al., "The consequences for renal function of widening of the interstitium and changes in the tubular epithelium of the renal cortex and outer medulla in various renal diseases," *Clinical Nephrology*, 37(2):70-77 (1992).

Kitching et al., "Interleukin-4 and interleukin-10 attenuate established crescentic glomerulonephritis in mice," *Kidney International*, 52:52-59 (1997).

Rui-Mei et al., "Dysregulation of cytokine expression in tubulointerstitial nephritis associated with murine malaria," *Kidney International*, 53:845-852 (1998).

Fiorentino et al., "Two types of mouse T helper cell. IV. Th2 clones secrete a factor that inhibits cytokine production by Th1 clones," *J Exp Med*, 170:2081-2095 (1989).

De Waal Malefyt et al., 'Interleukin 10 (IL-10) and viral IL-10 strongly reduce antigenspecific human T cell proliferation by diminishing the antigen-presenting capacity of monocytes via downregulation of class II major histocompatibility complex expression," *J* Exp Med, 174:915-924 (1991).

Irwin et al., "Effects of enalapril on adriamycin-induced nephrosis," *Pediatr Nephrol*, 6:448-450 (1992).

Taal et al., "Proinflammatory gene expression and macrophage recruitment in the rat remnant kidney," *Kidney International*, 58:1664-1676 (2000).

Chen et al., "Alterations of glomerular and extracellular glutathione peroxidase levels in patients and rats with focal segmental glomerulosclerosis," *J Lab Clin Med*, 137:279-283 (2001).

Ratschek et al., "Decompensated benign nephrosclerosis and secondary malignant nephrosclerosis," *Clin Nephrol*, 25:221-226 (1986).

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Engelhardt et al., "Interleukin-10 and Phenomena of Tolerance in Interleukin-2 Therapy," *J Clin Oncol*, 14:1405 (1996).

Matsumoto et al., "Spontaneous and lipopolysaccharide-stimulated secretion of cytokines by peripheral blood monocytes in IgA nephropathy is inhibited by interleukin-10," *Nephron*, 73:305-309 (1996).

Go et al., "Interleukin 10, a novel B cell stimulatory factor: unresponsiveness of X chromosome-linked immunodeficiency B cells," *J Exp Med*, 172:1625-1631 (1990).

It is respectfully requested that the Examiner indicate consideration of the cited references by returning copies of the attached form PTO/SB/08B (substitute for form 1449/PTO) with initials or other appropriate marks, and that the references be made of record as cited references in the application.

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**PATENT** 57354-08USA

Respectfully submitted,

December 14, 2006

Date

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PTO/SB/08B (08-03)
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Substitute for form 1448/210				Application Number	10/634,408		
INFO	ORMATION	DIS	CLOSURE	Filing Date	August 5, 2003		
STATEMENT BY APPLICANT			PPLICANT	First Named Inventor	Jong-gu PARK		
(Use as many sheets as necessary)				Art Unit	1633		
(USE as many sheets as necessary)			eccessary)	Examiner Name	Kelly, Robert M.		
Sheet	1	of	2	Attorney Docket Number	57354-08USA		

		NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. <sup>1</sup>			
	C1	KAMANNA et al., "Hyperlipidemia and kidney disease: Concepts derived from histopathology and cell biology of the glomerulus," Histol Histopathol, 13:169-179 (1998).		
	C2	DEL PRETE et al., "Molecular Biology of Diabetic Glomerulosclerosis," Nephrol Dial Transplant, 13(8):20-25 (1998).		
	С3	WEHRMANN et al., "Long-term prognosis of focal sclero-Sing glomerulonephritis. An analysis of 250 cases with particular regard to tubulointerstitial changes," Clinical Nephrology, 33(3):115-122 (1990).		
	C4	MACKENSEN-HAEN et al., "The consequences for renal function of widening of the interstitium and changes in the tubular epithelium of the renal cortex and outer medulla in various renal diseases," Clinical Nephrology, 37(2):70-77 (1992).		
	C5	KITCHING et al., "Interleukin-4 and interleukin-10 attenuate established crescentic glomerulonephritis in mice," Kidney International, 52:52-59 (1997).		
	C6	RUI-MEI et al., "Dysregulation of cytokine expression in tubulointerstitial nephritis associated with murine malaria," Kidney International, 53:845-852 (1998).		
	C7	FIORENTINO et al., "Two types of mouse T helper cell. IV. Th2 clones secrete a factor that inhibits cytokine production by Th1 clones," J Exp Med, 170:2081-2095 (1989).		
	C8	DE WAAL MALEFYT et al., "Interleukin 10 (IL-10) and viral IL-10 strongly reduce antigen-specific human T cell proliferation by diminishing the antigen-presenting capacity of monocytes via downregulation of class II major histocompatibility complex expression," J Exp Med, 174:915-924 (1991).		
	C9	IRWIN et al., "Effects of enalapril on adriamycin-induced nephrosis," Pediatr Nephrol, 6:448-450 (1992).		
	C10	TAAL et al., "Proinflammatory gene expression and macrophage recruitment in the rat remnant kidney," Kidney International, 58:1664-1676 (2000).		

Examiner	 Date	
Signature	 Considered	

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				Application Number	10/634,408	: <u>=</u>	
INFORMATION DISCLOSURE				Filing Date August 5, 2003			
STA	STATEMENT BY APPLICANT			First Named Inventor	Jong-gu PARK		
				Art Unit .	1633		
(Use as many sheets as necessary)			ecessary)	Examiner Name	Kelly, Robert M.		
Sheet	2	of	2	Attorney Docket Number	57354-08USA		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C11	CHEN et al., "Alterations of glomerular and extracellular glutathione peroxidase levels in patients and rats with focal segmental glomerulosclerosis," J Lab Clin Med, 137:279-283 (2001).	
	C12	RATSCHEK et al., "Decompensated benign nephrosclerosis and secondary malignant nephrosclerosis," Clin Nephrol, 25:221-226 (1986).	
	C13	BOHLE et al., "Is there any tubular secretion of protein?," Clin Nephrol, 29 (1):28-34 (1988).	
. 4.4	C14	ENGELHARDT et al., "Interleukin-10 and Phenomena of Tolerance in Interleukin-2 Therapy," J Clin Oncol, 14:1405 (1996).	
<del></del>	C15	MATSUMOTO et al., "Spontaneous and lipopolysaccharide-stimulated secretion of cytokines by peripheral blood monocytes in IgA nephropathy is inhibited by interleukin-10," Nephron, 73:305-309 (1996).	
	C16	GO et al., "Interleukin 10, a novel B cell stimulatory factor: unresponsiveness of X chromosome-linked immunodeficiency B cells," J Exp Med, 172:1625-1631 (1990).	

Examiner	/Robert Kelly/ (04/25/2008)	Date	/Robert Kelly/ (04/25/2008)
Signature	Thought Nonyi (o lize) 2000y	Considered	, , , , , , , , , , , , , , , , , , ,

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